

NOV 20 2013

K131689
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510(k) Summary
[as required by section 807.92(c)]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

General Information

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Date Prepared: June 25, 2013

Device Name

Trade Name: MRI Marker™
Common Name(s): Accessory to applicator and accessory to brachytherapy source

Classification

Regulation: 21 CFR §892.5730
Class: Class II
Product Code: KXX
Classification Name: System, applicator, radionuclide manual & Source, brachytherapy, radionuclide (accessory to); Radionuclide brachytherapy source

Predicate Devices

RP Spacer	K103449	Riverpoint Medical
Worldwide Medical Technologies Anchor Marker	K083274	Biocompatibles
Accu-Space™ Absorbable Seeding Spacer	K010621	CP Medical
Optisource ¹⁰³	K040766	IBt s.a.

Device Description

C4 Imaging's MRI Marker™ consists of a sealed polyether ether ketone (PEEK) polymer capsule containing a cobalt chloride:N-Acetylcysteine (CoCl₂:NAC) solution. It is used as an accessory to radionuclide sources (seeds) during prostate brachytherapy procedures. The length of the capsule is 5.5 mm and the diameter is 0.8 mm.

Indications

The MRI Marker is a component device indicated as an accessory for use in conjunction with brachytherapy seed carrier sleeves and radionuclide brachytherapy seeds containing one of the following isotopes: Iodine 125 (¹²⁵I), Palladium 103 (¹⁰³Pd) or Cesium 131 (¹³¹Cs). It is indicated for permanent interstitial implantation in the prostate of patients with confirmed prostatic malignancy.

Comparison to Predicate Devices

The proposed device, MRI Marker, is a seed spacer intended to maintain spacing between radioactive seeds when delivered by a preloaded seeding needle. Similarly, three of the predicate devices (RP Spacer, Anchor Marker, and Accu-Space Absorbable Seeding Spacer) are intended to maintain spacing between radioactive seed when delivered by a seeding needle. Both the MRI Marker and Anchor Marker are intended to facilitate the anatomical localization of seeds.

The RP Spacer has a similar intended use as the MRI Marker; as a brachytherapy accessory indicated to be placed between seeds in a carrier sleeve that facilitates the implant of seeds at predetermined intervals within body tissue. RP Spacers are composed of copolymer made from 90% glycolide and 10% L-lactide (PLGA). The MRI Marker consists of a sealed non-biodegradable, biocompatible polyether ether ketone (PEEK) polymer capsule containing a CoCl₂:NAC solution. Both the MRI Marker and the RP Spacer are available as sterile products with identical dimensions (5.5 mm in length and 0.8 mm in diameter).

The Anchor Marker has a similar intended use as an accessory component of a brachytherapy system intended to provide clear identification of anatomic regions by providing reference positions around the proposed treatment site. The Anchor Marker is intended to be implanted in a carrier sleeve in a manner identical to the MRI Marker. The Anchor Marker has similar technological characteristics to the MRI

Marker in that the active element is encapsulated in a synthetic biocompatible polymer and has identical dimensions (5.5 mm in length and 0.8 mm in diameter). The Anchor Marker active element is a Gold Fiducial Marker. Both the MRI Marker and the Anchor Marker can be visualized when imaged with MR and facilitate locating radioactive seeds.

CP Medical Accu-Space Absorbable Seeding Spacer is similar in that it is intended to maintain spacing between radioactive seeds when delivered by a preloaded seeding needle. The Accu-Space Absorbable Seeding Spacer consists of absorbable spacer material and is a small cylindrical component device.

Optisource¹⁰³ has similar technological characteristics to the MRI Marker, with the outer shell comprised of the same biocompatible polymer: polyether ether ketone (PEEK). As is the case with the MRI Marker the PEEK shell is sealed through heat induced welding to contain an active element. Optisource¹⁰³ is a permanent interstitial implant 5.0 mm long by 0.88 mm in diameter with a polymeric shell and containing Pd-103 in two solid polymeric cylinders separated by a gold marker to provide MRI visibility. The MRI Marker exhibits a positive signal when imaged with MR.

Performance Testing

In Vitro and *In vivo* preclinical testing was performed to verify and validate the safety and effectiveness of the MRI Marker. These tests included sterilization validation to ISO 11137; biocompatibility testing per ISO 10993-1; MRI safety testing per ASTM F2052, F2213, F2119, and F2182; and radiographic visualization.

Sterilization conditions have been validated in accordance to provide a Sterility Assurance Level (SAL) of 10^{-6} .

In vivo and *in vitro* tests were performed to address irritation, sensitization, cytotoxicity, sub-acute and sub-chronic toxicity, and implantation. Results identified the MRI Marker as a nonirritant, and nontoxic with no concerns for long-term safety.

The results of the MRI compatibility testing indicate that, in accordance with the guidance of relevant ASTM standards, the MRI marker should be labeled MR Conditional. There was no induced displacement force or torque observed for the device, and therefore, is not expected to pose a hazard.

Phantom prostate imaging testing produced a positive-signal MRI image demonstrating the ability of the MRI Marker to perform the intended use of facilitating localization of adjacent radioactive seeds. X-ray imaging of the seeds and MRI Markers loaded in strands and brachytherapy needles demonstrated the MRI Marker performed as intended in effectively spacing the seeds.

Animal testing indicates that the MRI Markers has a very low potential for toxicity.

Conclusion

The technological characteristics are similar to or equivalent to the predicate devices. Differences in design between the devices do not raise any new issues of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

C4 Imaging LLC
% Stephen J. Goldner, JD, RAC
President
Regulatory Affairs Associates, Inc.
2550 South Telegraph Road
BLOOMFIELD HILLS MI 48302

November 20, 2013

Re: K131689
Trade/Device Name: C4 Imaging MRI Marker
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KKK
Dated: October 7, 2013
Received: October 11, 2013

Dear Mr. Goldner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Michael D. O'Hara". The signature is written in a cursive style with a large, stylized "M" and "O".

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131689

Device Name: MRI Marker

Indications for Use:

The MRI Marker is a component device indicated as an accessory for use in conjunction with brachytherapy seed carrier sleeves and radionuclide brachytherapy sources containing one of the following isotopes: Iodine 125 (^{125}I), Palladium 103 (^{103}Pd) or Cesium 131 (^{131}Cs). It is indicated for permanent interstitial implantation in the prostate of patients with confirmed prostatic malignancy.

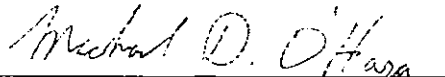
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)

Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131689